

2

AD-A240 698



DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1a. REPORT SECURITY CLASSIFICATION Unclassified		1b. RESTRICTIVE MARKINGS	
2a. SECURITY CLASSIFICATION AUTHORITY		3. DISTRIBUTION / AVAILABILITY OF REPORT Approved for public release; distribution is unlimited.	
2b. DECLASSIFICATION / DOWNGRADING SCHEDULE		5. MONITORING ORGANIZATION REPORT NUMBER(S)	
4. PERFORMING ORGANIZATION REPORT NUMBER(S) USAFSAM-JA-88-30		7a. NAME OF MONITORING ORGANIZATION	
6a. NAME OF PERFORMING ORGANIZATION USAF School of Aerospace Medicine	6b. OFFICE SYMBOL (If applicable) USAFSAM/EK	7b. ADDRESS (City, State, and ZIP Code)	
6c. ADDRESS (City, State, and ZIP Code) Human Systems Division (AFSC) Brooks AFB, TX 78235-5301		9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER	
8a. NAME OF FUNDING / SPONSORING ORGANIZATION USAF School of Aerospace Medicine	8b. OFFICE SYMBOL (If applicable) USAFSAM/EK	10. SOURCE OF FUNDING NUMBERS	
8c. ADDRESS (City, State, and ZIP Code) Human Systems Division (AFSC) Brooks AFB, TX 78235-5301		PROGRAM ELEMENT NO 87714F	PROJECT NO SUPT
		TASK NO XX	WORK UNIT ACCESSION NO EK
11. TITLE (Include Security Classification) Empty Sample Cups May Mimic Patient Results with the Stratus Analyzer			
12. PERSONAL AUTHOR(S) Armbruster, David A., and Jirinzu, David C.			
13a. TYPE OF REPORT Interim	13b. TIME COVERED FROM 88/2 TO 88/4	14. DATE OF REPORT (Year, Month, Day) 1988	15. PAGE COUNT 1
16. SUPPLEMENTARY NOTATION Article submitted to <u>Clinical Chemistry</u> , 34: 1931 (1988)			
17. COSATI CODES		18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number)	
FIELD	GROUP	SUB-GROUP	
06	05		
06	12		
		Immunoassay, Stratus Analyzer, Medical Laboratory Equipment, Errors, Sample Cups, False Low Values	
19. ABSTRACT (Continue on reverse if necessary and identify by block number) The 'Stratus' analyzer (Dade, Miami, FL) is a very automated clinical chemistry instrument which is capable of performing a wide variety of analyses. It does require laboratory technicians to load serum samples into specimen cups to be placed in the sample carousel. If an error is made and an empty sample cup is loaded onto the 'Stratus', a result may be printed which can be mistaken for a believable patient value. We have found this to be true for ferritin, free T4, HCG, IgE, and TSH. Care must be taken by the technician to insure that each cup contains patient specimen to avoid a possible erroneous interpretation if an empty cup is analyzed and the 'Stratus' prints a result on it.			
20. DISTRIBUTION / AVAILABILITY OF ABSTRACT <input checked="" type="checkbox"/> UNCLASSIFIED / UNLIMITED <input type="checkbox"/> SAME AS RPT <input type="checkbox"/> DTIC USERS		21. ABSTRACT SECURITY CLASSIFICATION Unclassified	
22a. NAME OF RESPONSIBLE INDIVIDUAL David A. Armbruster		22b. TELEPHONE (include Area Code) (512) 536-3671	22c. OFFICE SYMBOL USAFSAM/EK

Empty Sample Cups May Mimic Patients' Results with the Stratus Analyzer, *Dave Armbruster and David C. Jirinzu* (Clin. Chem. Section, Epidemiol. Div., USAF School of Aerospace Medicine, Human Systems Division (AFSC), Brooks AFB, TX 78235-5301)

The "Stratus" analyzer (American Dade, Miami, FL), introduced in 1982, is based upon the radial partition immunoassay methodology (1). We use it as a batch analyzer for 50 or more samples. Because specimen containers of various sizes are received in our reference laboratory, the sample cups for the 30-place Stratus carousel must be loaded by hand rather than with the instrument's automated sample handler. Occasionally an empty sample cup has inadvertently been loaded into a carousel and subsequently processed by the analyzer. Empty sample cups produce results that may be mistaken for patients' values, normal or abnormal, as shown below for the five tests we perform using the Stratus:

Test	Stratus reading			Normal ref. interval
	Empty cup	Distilled water	Zero calibrator	
Ferritin ($\mu\text{g/L}$)	<0	1.4	0	30-300 (male) 10-200 (female)
Free T_4 (pmol/L)	4.6	2.6	0	11.6-27.1
HCG (int. units/L)	6.2-6.3	8-9.1	0	<25
IgE (g/L)	3.6	5.6	0	3-423
Thyrotropin (milli-int. units/L)	3.3-4.0	4.6-5.3	0	0.35-7.0

An empty sample cup may result in an erroneous value being reported for a patient. In the case of ferritin, a diagnosis of iron deficiency anemia would be indicated if a value of zero is reported. A hypothyroid condition is suggested by a free T_4 value less than 11.5 pmol/L. Typically non-pregnant women produce a zero result for choriogonadotropin (HCG) with the Stratus, with a value falling between 25 and 50 int. units/L being considered borderline for pregnancy, a value near 6 would be considered to be negative. An IgE value of 3-4 g/L is consistent with a low-normal result. Thyrotropin values between 3 and 4 milli-int. units/L, as produced by an empty sample cup, fall in the middle of the normal reference interval.

Stratus assays require the presence of protein to function properly, as shown by the values obtained with empty sample cups and with distilled water. Stratus zero calibrators, prepared in processed human serum, produce the expected results. To eliminate this problem, visual inspection of the sample cups is required before the carousel is loaded into the instrument.

Reference

1. Giegel JL, Brotherton MM, Cronin P, et al. Radial partition immunoassay. Clin Chem 1982;28:1894-8.

[Reprinted from CLINICAL CHEMISTRY, 34, 1931 (1988).]

Copyright 1988 by the American Association of Clinical Chemistry and reprinted by permission of the copyright owner.

RECEIVED BY
DATE
TIME
BY
INITIALS
A-1 20

91-11027